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# APPLICATION FOR UNITED STATES LETTERS PATENT

for

## **IMPLANTED MEDICAL DEVICE TELEMETRY USING INTEGRATED THIN FILM BULK ACOUSTIC RESONATOR FILTERING**

by

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## IMPLANTED MEDICAL DEVICE TELEMETRY USING INTEGRATED THIN FILM BULK ACOUSTIC RESONATOR FILTERING

This application is a continuation-in-part of co-pending, commonly assigned U.S. Patent Application S. N. 09/648,604 filed August 16, 2000, in the names of G. Haubrich et al. for Implanted Medical Device Telemetry Using Integrated Microelectromechanical Filtering.

### FIELD OF THE INVENTION

This invention relates to the field of implantable medical devices and particularly to implantable devices that use a high-performance RF telemetry communication link for the transfer of information in cooperation with an external programming unit.

### BACKGROUND OF THE INVENTION

Since the introduction of the first implantable pacemakers in the 1960s, there have been considerable advancements in both the field of electronics and of medicine, such that there is presently a wide assortment of commercially available body-implantable electronic medical devices. The class of implantable medical devices now includes pacemakers, but also implantable cardioverters, defibrillators, neural stimulators, drug administering devices, insertable loop recorders, or physiologic monitors among others. Today's state-of-the-art implantable medical devices are vastly more sophisticated and complex than early ones, capable of performing significantly more complex tasks. The therapeutic benefits of such devices have been well proven.

As the functional sophistication and complexity of implantable medical device systems have increased over the years, it has become increasingly more important to include a system for facilitating communication between one implanted device and another implanted or external device, for example, a programming console, monitoring system, or the like.

Shortly after the introduction of the earliest fixed-rate, non-inhibited pacemakers, it became apparent that it would be desirable for physicians to non-invasively obtain information regarding the operational status of the implanted device, and/or to exercise at least some control over the device, e.g., to turn the device on or off

5 or adjust the fixed pacing rate, after implant. Initially, communication between an implanted device and the external world was primarily indirect. For example, information about the operational status of an implanted device could be communicated via the electrocardiogram of the patient by modulating the rate of delivery of stimulating pulses in some manner. This was the case for the Medtronic Spectrax™, circa 1979, for which a 10% change in pacing rate was used to indicate battery status. This method could only provide a very low data rate transmission without interfering with the clinical application of the device. An early method for communicating information to an implanted device was through the provision of a magnetic reed switch in the implantable device. After implant, placing a magnet over the implant site would actuate the reed switch. Reed switch closure could then be used, for example, to alternately activate or deactivate the device. Alternatively, the fixed pacing rate of the device could be adjusted up or down by incremental amounts based upon the duration of reed switch closure.

10 15 Over time, many different schemes utilizing a reed switch to adjust parameters of implanted medical devices have been developed. See, for example, U.S. Patent No. 3,311,111 to Bowers, U.S. Patent No. 3,518,997 to Sessions, U.S. Patent No. 3,623,486 to Berkovits, U.S. Patent No. 3,631,860 to Lopin, U.S. Patent No. 3,738,369 to Adams et al., U.S. Patent No. 3,805,796 to Terry, Jr., and U.S. Patent No. 4,066,086 to Alfernness et al.

20 25 As new, more advanced features have been incorporated into implantable devices, it has been increasingly necessary to convey correspondingly more information to the device relating to the selection and control of those features. For example, if a pacemaker is selectively operable in various pacing modes (e.g., VVI, VDD, DDD, etc.), it is desirable that the physician or clinician be able to non-invasively select a mode of operation. Similarly, if the pacemaker is capable of pacing at various rates, or of delivering stimulating pulses of varying energy levels, it is desirable that the physician or clinician be able to select, on a patient-by-patient basis, appropriate values for such variable operational parameters.

30 Even greater demands are placed upon the communication system in implantable devices having such advanced features as rate adaptation based upon activity sensing, as disclosed, for example, in U.S. Patent No. 5,052,388 to Sivula et al. entitled "Method

and Apparatus for Implementing Activity Sensing in a Pulse Generator", or in U.S. Patent No. 5,271,395 to Wahlstrand et al. entitled "Method and Apparatus for Rate-Responsive Cardiac Pacing." The Sivula et al. '388 and Wahlstrand et al. 395 patents are each hereby incorporated by reference herein in their respective entireties.

The information communicated to the implantable device in today's state-of-the-art pacemakers can include: pacing mode, multiple rate response settings, electrode polarity, maximum and minimum pacing rates, output energy (output pulse width and/or output pulse amplitude), sense amplifier sensitivity, refractory periods, calibration information, rate response attack (acceleration) and decay (deceleration), onset detection criteria, and many other parameter settings.

The need to be able to communicate more and more information to implanted devices (i.e., to establish "downlink" communication channels) quickly rendered the simple reed-switch closure arrangement inadequate. Also, it has become apparent that it would also be desirable not only to allow information to be communicated to the implanted device, but also to enable the implanted device to communicate information to the outside world (i.e., to establish "uplink" communication channels). (As used herein, the terms "uplink" and "uplink communication" will be used to denote the communications channel for conveying information from the implanted device to an external unit of some sort. Conversely, the terms "downlink" and "downlink communication" will be used to denote the communications channel for conveying information from an external unit to the implanted device. Although this terminology assumes that communication is occurring between an implanted device and an external device, it is contemplated that the communication system described herein is equally useful and beneficial in situations where communication occurs between any two or more devices, whether some are implanted and others are implanted, or all are implanted, or all are external.)

For diagnostic purposes, it is desirable for the implanted device to be able to communicate information regarding the device's operational status and the patient's condition to the physician or clinician. State of the art implantable devices are available which can even transmit a digitized electrical signal reflecting electrical cardiac activity (e.g., an ECG, EGM, or the like) for display, storage, and/or analysis by an external device. In addition, known pacemaker systems have been provided with what is referred

to as Marker Channel™ functionality, in which uplink information regarding the pacemaker's operation and the occurrence of physiological events is communicated to an external programming unit. The Marker Channel™ information can then be printed or displayed in relation to an ECG so as to provide supplemental information regarding pacemaker operation. For example, events such as pacing or sensing of natural heartbeats are recorded with a mark indicating the time of the event relative to the ECG. This is helpful to the physician in interpreting the ECG, and in verifying proper operation of the pacemaker. One example of a Marker Channel™ system is disclosed in U.S. Patent No. 4,374,382 to Markowitz, entitled "Marker Channel Telemetry System for a Medical Device." The Markowitz '382 patent is hereby incorporated by reference herein in its entirety.

Existing systems, which provide a Marker Channel™ output, operate basically by outputting an indication of a physiological or pacemaker event, e.g., a delivered stimulating pulse or a sensed heartbeat, at about the time of the event, thereby inherently providing the timing of the event in relation to the recorded ECG. Alternatively, the Marker Channel™ system can accumulate data over a period of time, e.g., one cardiac cycle, and transmit a batch of data for that interval at the beginning of the next interval. This is what appears to be proposed in U.S. Patent No. 4,601,291 to Boute et al., entitled "Biomedical System with Improved Marker Channel Means and Method."

Typically, communication with an implanted medical device (IMD) has been employed in conjunction with an external programming/processing unit. One programmer for non-invasively programming a cardiac pacemaker is described in its various aspects in the following U.S. Patents to Hartlaub et al., each commonly assigned to the assignee of the present invention and each incorporated by reference herein: U.S. Patent No. 4,250,884 entitled "Apparatus For and Method Of Programming the Minimum Energy Threshold for Pacing Pulses to be Applied to a Patient's Heart"; U.S. Patent No. 4,273,132 entitled "Digital Cardiac Pacemaker with Threshold Margin Check"; U.S. Patent No. 4,273,133 entitled Programmable Digital Cardiac Pacemaker with Means to Override Effects of Reed Switch Closure"; U.S. Patent No. 4,233,985 entitled "Multi-Mode Programmable Digital Cardiac Pacemaker"; U.S. Patent No. 4,253,466 entitled "Temporary and Permanent Programmable Digital Cardiac

Pacemaker"; and U.S. Patent No. 4,401,120 entitled "Digital Cardiac Pacemaker with Program Acceptance Indicator".

Aspects of the programmer that are the subject of the foregoing Hartlaub et al. patents (hereinafter "the Hartlaub programmer") are also described in U.S. Patent No. 4,208,008 to Smith, entitled "Pacing Generator Programming Apparatus Including Error Detection Means" and in U.S. Patent No. 4,236,524 to Powell et al., entitled "Program Testing Apparatus". The Smith '008 and Powell et al. '524 patents are also incorporated by reference herein in their entirety.

Heretofore, three basic techniques have been used for telemetered communication in an implantable device system: magnetic field coupling, reflected impedance coupling, and radio-frequency (RF) coupling. In static magnetic field coupling, of which the above-described Bowers '111 patent is an example, a static magnetic field is generated external to the medical device, e.g., using a permanent magnet, having sufficient strength to close a magnetic reed switch within the implanted device. While such a technique provides a fairly reliable mechanism for turning various functions within the implanted device on or off, the technique is, as noted above, much too slow for efficiently transferring any significant amount of data. Furthermore, for all practical purposes, the static magnetic system is useful only for downlink communication, not for uplink communication. Despite the limitations of magnetic coupling downlink communication, its simplicity and reliability are such that such arrangements can be found even in current devices, for example, the Medtronic Itrel II implantable neural stimulator, as substantially described in U.S. Patent No. 4,520,825 to Thompson et al.

Dynamic magnetic field programming, on the other hand, relies upon the generation of a series of strong magnetic impulses, which periodically actuate a magnetic reed switch inside the implanted device. The output of the reed switch circuit forms the programming input to data registers in the implantable device, as shown, for example, in the above-referenced to Terry, Jr. et al.'796 patent. Such arrangements have several limitations, including the rate at which strong magnetic impulses can be generated (several hundred hertz or so), the physical size of the reed switch and magnet, the sensitivity to magnetic field orientation, and necessity of generating the impulses in very close proximity to the implanted device.

In a reflected impedance coupling system, information is transferred using the reflected impedance of an internal (implanted) L-R or L-C circuit RF energized by an inductively coupled, external, L-R or L-C circuit. Such a system is shown, for example, in U.S. Patent No. 4,223,679 to Schulman et al. Advantageously, such a system uses little or no current to transmit information. Disadvantageously, however, the maximum data rate of reflected impedance-coupling systems is relatively slow, and the distance or rate at which information may be transferred is limited.

In RF coupled systems, which are perhaps the most commonly employed communication systems in modern implantable device systems, information is transferred from a transmitting coil to a receiving coil by way of a radio-frequency carrier signal. The carrier signal is modulated with the data that is to be transmitted using an appropriate modulation scheme, such as phase shift keying (PSK), frequency shift keying (FSK), or pulse position modulation (PPM), among numerous others. The modulated carrier induces a voltage in the receiving coil that tracks the modulated carrier signal. This received signal is then demodulated in order to recover the transmitted data. Because the stainless steel or titanium canister commonly used to hermetically enclose an implanted device acts as a low-pass filter for the transmitted RF signals, attenuation increases as frequency is increased. Devices currently on the market have a maximum frequency of less than 200-kHz. Also, the transmitting range has been limited to 2- to 3-inches or so.

High performance telemetry communications systems used in sensor and signaling applications allow a high level of integration, as every component of the telemetry system is realized in a single semiconductor integrated circuit. The lack of external tuned circuits in such telemetry systems dictates the use of a very broadband receiver front end with a high dynamic range, which makes the receiver especially susceptible to strong out-of-band electromagnetic interference (EMI) from such sources as television, FM and business bands, and two-way, cellular, or PCS radio transmitters. Though intermittent, EMI may potentially degrade the telemetry communications link. Additionally, EMI may overload or interfere with the implant's sensors and sensor amplifiers thereby causing spurious therapy outputs, or inhibiting required therapy output, based on erroneous sensor data. High-level (order) EMI interference detectors may be used to inhibit spurious therapy in this case. Alternately, RF (low-pass, high-

pass, or notch) filtering can also be applied to sensor inputs of the implant to filter out the EMI interference and retain normal device performance. However, retaining full telemetry link performance under large EMI interference requires attenuation of the interfering signal while not attenuating the telemetry signal. Typically this is done via RF band-pass filtering at the receiver front-end for strong out-of-band interferors. Additionally, a very narrow (at least one channel bandwidth) tunable preselector (band-pass) filter, or an RF notch filter can be used to reject narrow in-band or out-of-band interference. In this way, EMI interference to the telemetry link can be minimized or eliminated

The majority of front end high Q bandpass filters used in radio frequency (RF) and intermediate frequency (IF) stages of heterodyning transceivers use off-chip, mechanically resonant components such as crystal filters, helical filters, or surface acoustic wave (SAW) resonators. These greatly outperform comparable devices using transistor technologies in terms of insertion loss, percent bandwidth, and achievable rejection of noise signals. SAW resonators can be combined with signal processing and spread spectrum technologies for high rejection against jamming and interference. Advantages are high sensitivity, high reliability, and a moderate size of 1 cm<sup>2</sup>.

Off-chip components are required to interface with integrated components at the board level, which constitutes an important bottleneck to miniaturization and the performance of heterodyning transceivers. Recent attempts to achieve single chip transceivers have used direct conversion architectures, rather than heterodyning and have suffered in overall performance. The continued growth of micromachining technologies, which yield high -Q on-chip vibrating mechanical resonators now make miniaturized, single-chip heterodyning transceivers possible. Thin film bulk acoustic resonator (FBAR) yield ultra high Qs of over 80,000 under vacuum and center frequency temperature coefficients less than 10 ppm/<sup>0</sup>C and serve well as a substitute for crystal filters and SAW devices in a variety of high-Q oscillator and filtering applications. FBAR resonators are capable of frequency operation to GHz levels and filtering operation up to the 6<sup>th</sup> order.

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**SUMMARY OF THE INVENTION**

The present invention provides an implantable medical device, such as a cardiac pacemaker, having an RF transceiver that uses a thin film bulk acoustic resonator filter as an out-of-band interference rejection filter. The thin film bulk acoustic resonator filter is preferably implemented as a receiver front-end bandpass filter or notch filter. Furthermore, the present invention provides an implanted medical device having a multichannel RF transceiver wherein each channel includes a thin film bulk acoustic resonator filter and wherein a processor evaluates the noise level on each channel and selects the channel having the best signal-to-noise ratio for further communications.

The present invention yet further discloses the use of thin film bulk acoustic resonator filters in the RF transceiver of an external programming unit that communicates with an implanted medical device. Moreover, a thin film bulk acoustic resonator filter may be used in each channel of a multichannel RF transceiver in an external programming unit.

**BRIEF DESCRIPTION OF THE DRAWINGS**

Figure 1 is an illustration of an implanted medical device in the form of a cardiac pacemaker and an associated external programming unit.

Figure 2 is a block diagram depicting the various functional circuit blocks of the implanted pacemaker of Figure 1.

Figure 3 is a perspective view of the external programming unit of Figure 1.

Figure 4 is a block diagram of an RF telemetry transceiver for the telemetry circuit functional block shown in Figure 2.

Figure 5a is a cross sectional view of a layout for a thin film bulk acoustic resonator filter for use as an out-of-band interference rejection filter.

Figure 5b is an equivalent model of the thin film bulk acoustic resonator filter of Figure 5a.

Figure 6 is a schematic block diagram of an embodiment of a duplexer according to the invention.

Figure 7 is a block diagram of a multichannel RF telemetry receiver for use in the

implantable pacemaker and/or the external programming unit of Figure 1 and depicting the use of a thin film bulk acoustic resonator filter in the front end of each channel.

Figure 8 is a flow diagram outlining the steps in a microprocessor executable routine for evaluating the signal-to-noise ratio of each channel of the receiver shown in Figure 6 and for selecting the receiver channel having the best performance.

Figure 9 shows another embodiment of a multichannel receiver for an implantable pacemaker, which does not include the channel noise level evaluation function.

#### DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

The implantable medical device (IMD) system shown in Figure 1 includes, for example, an implantable pacemaker 10, which has been implanted in a patient 12. The pacemaker 10 is housed within a hermetically sealed, biologically inert outer canister or housing, which may itself be conductive so as to serve as an indifferent electrode in the pacemaker's pacing/sensing circuit. One or more pacemaker leads, collectively identified with reference numeral 14 in Figure 1 are electrically coupled to pacemaker 10 in a conventional manner and extend into the patient's heart 16 via a vein 18. Disposed generally near the distal end of leads 14 are one or more exposed conductive electrodes for receiving electrical cardiac signals or delivering electrical pacing stimuli to the heart 16. The leads 14 may be implanted with their distal end situated in either the atrium or ventricle of the heart 16.

Although the present invention is described herein in an embodiment that includes a pacemaker, it may be advantageously embodied in numerous other types of implantable medical device systems in which it is desirable to provide a communication link between two physically separated components.

Figure 1 also depicts an external programming unit 20 for non-invasive communication with implanted device 10 via uplink and downlink communication channels, to be hereinafter described in further detail. Associated with programming unit 20 is a programming head 22, in accordance with conventional medical device programming systems, for facilitating two-way communication between pacemaker 10 and programmer 20. In many known implantable device systems, a programming head such as that depicted in Figure 1 is positioned on the patient's body over the implant site

of the device (usually within 2- to 3-inches of skin contact), such that one or more antennas within the head can send RF signals to, and receive RF signals from, an antenna disposed within the hermetic enclosure of the implanted device or disposed within the connector block of the device, in accordance with common practice in the art.

Figure 2 provides a block diagram of the electronic circuitry that makes up pacemaker 10 for delivery of electrical stimulation therapy to the patient in accordance with the presently disclosed embodiment of the invention. Figure 2 shows that pacemaker 10 comprises circuitry for controlling the device's pacing and sensing functions. The pacemaker circuitry may be of conventional design, in accordance, for example, with what is disclosed the above-referenced Sivula et al. '388 patent. To the extent that certain components of the circuitry of pacemaker 10 are conventional in their design and operation, such components will not be described herein in detail, as it is believed that design and implementation of such components would be a matter of routine practice to those of ordinary skill in the art. For example, the circuitry of pacemaker 10 shown in Figure 2 includes sense amplifier circuitry 24, stimulating pulse output circuitry 26, a crystal clock 28, a random-access memory and read-only memory (RAM/ROM) unit 30, and a pacing timing and control circuit in the form of a programmed central processing unit (CPU) 32, all of which are well-known in the art.

Pacemaker 10 also includes internal telemetry communication circuit 34 coupled to antenna 36 so that it is capable of communicating with external programmer/control unit 20, as will be hereinafter described in greater detail. Various telemetry systems for providing the necessary uplink and downlink communication channels between an external programming unit and an implanted pacemaker have been shown in the art. Communication telemetry systems are disclosed, for example, in the following U.S. Patents: U.S. Patent No. 4,539,992 to Calfee et al. entitled "Method and Apparatus for Communicating With Implanted Body Function Stimulator;" U.S. Patent No. 4,550,732 to Batty Jr. et al. entitled "System and Process for Enabling a Predefined Function Within An Implanted Device;" U.S. Patent No. 4,571,589 to Slocum et al. entitled "Biomedical Implant With High Speed, Low Power Two-Way Telemetry;" U.S. Patent No. 4,676,248 to Berntson entitled "Circuit for Controlling a Receiver in an Implanted Device;" U.S. Patent No. 5,127,404 to Wyborny et al. entitled "Telemetry Format for Implanted Medical Device;" U.S. Patent No. 4,211,235 to Keller, Jr. et al. entitled

"Programmer for Implanted Device;" the above-referenced Markowitz '382 patent; and U.S. Patent No. 4,556,063 to Thompson et al. entitled "Telemetry System for a Medical Device." The Wyborny et al. '404 patent and the Thompson et al. '063 patent are hereby incorporated by reference herein in their respective entireties.

With continued reference to Figure 2, pacemaker 10 is coupled to one or more leads 14 which, when implanted, extend transvenously between the implant site of pacemaker 10 and the patient's heart 16, as previously noted with reference to Figure 1. Physically, the connections between leads 14 and the various internal components of pacemaker 10 are facilitated by a conventional connector block assembly 11, shown in Figure 1 but not shown in Figure 2. Electrically, the coupling of the conductors of leads and internal electrical components of pacemaker 10 may be facilitated by a lead interface circuit 19 which functions, in a multiplexer-like manner, to selectively and dynamically establish necessary connections between various conductors in leads 14, including, for example, atrial tip and ring electrode conductors ATIP and ARING and ventricular tip and ring electrode conductors VTIP and VRING, and individual electrical components of pulse generator 10, as would be familiar to those of ordinary skill in the art. For the sake of clarity, the specific connections between leads 14 and the various components of pacemaker 10 are not shown in Figure 2, although it will be clear to those of ordinary skill in the art that, for example, leads 14 will necessarily be coupled, either directly or indirectly, to sense amplifier circuitry 24 and stimulating pulse output circuit 26, in accordance with common practice, such that cardiac electrical signals may be conveyed to sensing circuitry 24, and such that stimulating pulses may be delivered to cardiac tissue, via leads 14. Also not shown in Figure 2 is the protection circuitry commonly included in implanted devices to protect, for example, the sensing circuitry of the device from high voltage stimulating pulses.

As previously noted, the circuitry of pacemaker 10 includes central processing unit (CPU) 32 which may be an off-the-shelf programmable microprocessor or microcontroller, but in the presently preferred embodiment of the invention is a custom integrated circuit. Although specific connections between CPU 32 and other components of the pacemaker circuitry are not shown in Figure 2, it will be apparent to those of ordinary skill in the art that CPU 32 functions to control the timed operation of stimulating pulse output circuit 26 and sense amplifier circuit 24 under control of

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program of instructions stored in RAM/ROM unit 30. Crystal oscillator circuit 28 in the presently preferred embodiment is a 32,768-Hz crystal controlled oscillator that provides main timing clock. Again, the lines over which such clocking signals are provided to the various timed components of pacemaker 10 (e.g., microprocessor 32) are omitted from Figure 2 for the sake of clarity. It is believed that those of ordinary skill in the art will be familiar with such an operative arrangement.

It is to be understood that the various components of pulse generator 10 depicted in Figure 2 are powered by means of a battery (not shown), which is contained within the hermetic enclosure of pacemaker 10, in accordance with common practice in the art. For the sake of clarity in the drawings, the battery and the connections between it and the other components of pacemaker 10 are not shown.

Stimulating pulse output circuit 26, which functions to generate cardiac stimuli under control of signals issued by CPU 32, may be, for example, of the type disclosed in U.S. Patent No. 4,476,868 to Thompson, entitled "Body Stimulator Output Circuit," which patent is hereby incorporated by reference herein in its entirety. Again, however, it is believed that those of ordinary skill in the art could select from among many various types of prior art pacing output circuits, which would be suitable for the purposes of practicing the present invention.

Sense amplifier circuit 24, may be, for example, of the type disclosed in US Patent No. 4,357,943 to Thompson, entitled "Demand Cardiac Pacemaker Having Reduced Polarity Disparity," which patent is hereby incorporated by reference herein in its entirety; functions to receive electrical cardiac signals from leads 14 and to process such signals to derive event signals reflecting the occurrence of specific cardiac electrical events, including atrial contractions (P-waves) and ventricular contractions (R-waves). These event-indicating signals are provided to CPU 32 for use by the CPU in controlling the synchronous stimulating operations of pulse generator 10 in accordance with common practice in the art. In addition, these event-indicating signals may be communicated, via uplink transmission, to external programming unit 20 for visual display to a physician or clinician.

Those of ordinary skill in the art will appreciate that pacemaker 10 may include numerous other components and subsystems, for example, activity sensors and associated circuitry. The presence or absence of such additional components in

pacemaker 10, however, is not believed to be pertinent to the present invention, which relates primarily to the implementation and operation of telemetry block 34 in pacemaker 10, and an associated RF transceiver in external programming unit 20.

Figure 3 shows a perspective view of a programming unit 20 in accordance with the presently disclosed embodiment of the invention. Internally, programmer 20 includes a processing unit (not shown in the Figures), which in accordance with the presently disclosed embodiment of the invention is a personal computer type motherboard, e.g., a computer motherboard including an Intel 80x86 microprocessor and related circuitry such as digital memory. The details of design and operation of the programmer's computer system will not be set forth in detail in the present disclosure, as it is believed that such details are well-known to those of ordinary skill in the art.

Referring to Figure 3, programmer 20 comprises an outer housing 60, which is preferably made of thermal plastic or another suitably rugged yet relatively lightweight material. A carrying handle, designated generally as 62 in Figure 3, is integrally formed into the front of housing 60. With handle 62, programmer 20 can be carried like a briefcase.

An articulating display screen 64 is disposed on the upper surface of housing 60. Display screen 64 folds down into a closed position (not shown) when programmer 20 is not in use, thereby reducing the size of programmer 20 and protecting the display surface of display 64 during transportation and storage thereof.

A floppy disk drive is disposed within housing 60 and is accessible via a disk insertion slot (not shown). A hard disk drive is also disposed within housing 60, and it is contemplated that a hard disk drive activity indicator, (e.g., an LED, not shown) could be provided to give a visible indication of hard disk activation.

As would be appreciated by those of ordinary skill in the art, it is often desirable to provide a means for programmer 20 to adapt its mode of operation depending upon the type of implanted device to be programmed. Accordingly, it may be desirable to have an expansion cartridge containing EPROMs or the like for storing program information to control programmer 20 to operate in a particular manner corresponding to a given type of implantable device.

In accordance with the preferred embodiment of the invention, programmer 20 is equipped with an internal printer (not shown) so that a hard copy of a patient's ECG or

of graphics displayed on the programmer's display screen 64 can be generated. Several types of printers, such as the AR-100 printer available from General Scanning Co., are known and commercially available.

In the perspective view of Figure 3, programmer 20 is shown with articulating display screen 64 having been lifted up into one of a plurality of possible open positions such that the display area thereof is visible to a user situated in front of programmer 20. Articulating display screen is preferably of the LCD or electro-luminescent type, characterized by being relatively thin as compared, for example, a cathode ray tube (CRT) or the like.

Display screen 64 is operatively coupled to the computer circuitry disposed within housing 60 and is adapted to provide a visual display of graphics and/or data under control of the internal computer.

Programmer 20 described herein with reference to Figure 3 is described in more detail in U.S. Patent No. 5,345,362 issued to Thomas J. Winkler, entitled "Portable Computer Apparatus With Articulating Display Panel," which patent is hereby incorporated herein by reference in its entirety. Also, the Medtronic Model 9760 or 9790 programmers are other implantable device programming units with which the present invention may be advantageously practiced.

An RF transceiver for use as the telemetry block 34 in pacemaker 10 is shown in Figure 4. The UHF RF Transceiver shown in figure 4 consists of the following main functional blocks: a "Zero-IF" Receiver (404 through 430 and 436), an FSK Transmitter (438 and 440), and a UHF Frequency Synthesizer 432 & 434) providing both Local Oscillator injection to the receiver's UHF mixer and a FM modulated frequency source for the transmitter.

The Zero-IF Receiver consists of a T/R switch (404) (RF switching transistor structure, or an RF MEMS switch) to route the RF energy received from the Implanted Antenna (402) to the Preselector Filter (406). The Preselector Filter may consist of either a UHF SAW Bandpass Filter or an RF FBAR Bandpass Filter. The SAW Filter would be external to the die, while the RF FBAR Filter could be integrated on the RF IC die. The function of the Preselector Filter is to reject all out-of-band RF signals such as AM, FM, TV Broadcasting, Two-way Radio, and Cellular Phones, etc., and allow only the desired Telemetry Frequency Band of interest to pass unattenuated to

the receiver's Low Noise Amplifier, or LNA, (408) input. This prevents strong RF interference from overloading the receiver's RF front-end, while allowing the weaker telemetry signal to be received with no apparent interference.

The LNA has a very low inherent noise floor and amplifies the desired weak RF telemetry signal prior to sending it on to the two UHF Mixers (410 and 424). As seen in figure 4, the LNA output is fed equally to two UHF Mixers. The purpose of two mixers is to generate INPHASE and QUADRATURE baseband IF (Intermediate Frequency) signals which can be processed for an FM demodulation function. The INPHASE Mixer (410) has the LO injection phase shifted -90 degrees by the LO phase-shifter (422), with the QUADRATURE Mixer (424) having the LO fed INPHASE from the LO phase-shifter. The baseband output of these two mixers are thus in phase quadrature with each other (an I and a Q IF channel). The IF filtering and amplification occur in two identical parallel paths: one containing the I Channel, and the second the Q Channel. The UHF Mixer outputs feed two "roofing filters" (412 & 426), which consist of an on-chip active low-pass filter slightly wider than the channel bandwidth (these filters could also be implemented as a low frequency FBAR bandpass filter). These filters improve the apparent Intermodulated Distortion performance of the following IF stages. The signal flows from the roofing filter output to two IF amplifiers (414 & 428) which amplify the IF signal prior to filtering by the IF channel low-pass filters (416 & 430) which set the effective communications channel bandwidth. These filters are currently on-chip active low-pass FBAR filters, but they could also be implemented with on-chip lower frequency bandpass FBAR filters.

The output of the IF channel filters is passed to the limiter amplifiers (418 & 436) which amplify the downconverted and filtered received signal until limiting occurs. This digital signal is then processed via the digital signal processing in the Digital Demodulator, Bit-Sync, and Signal Processing circuitry (420) to provide both serial data output and a synchronous clock output.

The UHF Frequency Synthesizer (432 & 434) is a single loop phase locked loop which phase locks the UHF VCO (432) to a crystal reference oscillator. The frequency control element for the open-loop UHF VCO may be an on-chip, or off-chip, L-C tank with varactor tuning, or an on-chip tunable RF FBAR resonator. The

PLL uses programmable dividers to provide for channel changes and control of the UHF VCO via a closed loop control system using the UHF VCO frequency control input as the control means.

The UHF Transmitter simply takes the output of the frequency synthesizer, amplifies it (via 440), and sends it through the T/R switch to the Implanted Antenna. TX modulation is accomplished by directly Frequency Modulating the UHF VCO via a Lowpass Data Filter (438) to limit the transmitter bandwidth.

The FBAR filters described above in reference to the transceiver shown in FIG. 4 may be as described in U.S. Pat. Nos. 6,198,208, 6,215,375 and/or 6,262,637 all incorporated herein by reference in their entireties. An example of an FBAR 150 in cross section is shown in FIG. 5A.

The FBAR 150 is composed of the piezoelectric layer 152 suspended at its periphery over the well 154 defined by the substrate 156. The electrodes 158 and 160 are located on opposite surfaces of the portion of the piezoelectric layer that overlaps the well. Electrical connections are made to the electrodes 158 and 160 via the terminals 166 and 168, respectively. The piezoelectric layer 152 and the electrodes 158 and 160 form the piezoelectric resonator stack 162. The piezoelectric resonator stack expands and contracts in the direction indicated by the arrow 164 in response to the magnitude and direction of a voltage applied between the electrodes.

When the piezoelectric resonator stack 162 composed of the piezoelectric layer 152 and the electrodes 158 and 160 is suspended at its periphery and has both of its major surfaces in contact with air, other ambient gas or vacuum, the piezoelectric resonator stack forms a high-Q acoustic resonator. An AC signal applied via the terminals 166 and 168 to the electrodes 158 and 160 will cause the piezoelectric resonator stack to resonate when the signal has a frequency equal to the velocity of sound in the piezoelectric resonator stack divided by twice the weighted thickness of the stack, i.e.,  $f_r = c/2t_0$ , where  $f_r$  is the resonant frequency,  $c$  is the velocity of sound in the stack and  $t_0$  is the weighted thickness of the stack. The resonant frequency of the piezoelectric resonator stack depends on the weighted thickness of the stack rather than the physical thickness because the different velocity of sound in the materials constituting the stack.

In one embodiment of the FBAR 150 with a resonance at about 1,900 MHz, the substrate 156 is a wafer of single-crystal silicon, the piezoelectric layer 152 is a layer of aluminum nitride (AlN) about 2  $\mu\text{m}$  thick and the electrodes 158 and 160 are layers of molybdenum about 0.1  $\mu\text{m}$  thick. Molybdenum is the preferred material for the electrodes because, in this thin-film embodiment, the electrodes constitute a significant portion of the mass of the piezoelectric resonator stack 162. Thus, the acoustic properties of the material of the electrodes have a significant effect on the Q of the piezoelectric resonator stack. Molybdenum has superior acoustic properties to those of common electrode materials such as gold and aluminum, so molybdenum electrodes enable the FBAR 150 to have a higher Q than electrodes of other materials. Electrode 158 overlies at least a portion of the second electrode 168, the portion of electrode 158 that overlies electrode 168 determines the electric field distribution. The resulting planar shape of electric field may be designed to have a periphery which is a non-rectangular, irregular polygon, the periphery forming a quadrilateral shape in which no two sides are parallel to one another. This design, as substantially described in U.S. Patent No. 6,215,375 incorporated herein by reference in its entirety, minimizes parasitic oscillation modes traveling parallel to the plane of the electrodes and bouncing off the walls of the cavity 154 or the discontinuity at the edge of the electrode layers.

FIG. 5B shows an equivalent circuit for the FBAR 150. The main reactive component is the shunt capacitance  $C_p$ , which is the capacitance of the capacitor formed by the electrodes 158 and 160 and the piezoelectric layer 152. The piezoelectric layer is the dielectric of the shunt capacitor  $C_p$ . The resistor  $R_p$  represents the series resistance of the shunt capacitance  $C_p$ . The inductance  $L_M$  and the capacitance  $C_M$  represent the inductance and capacitance of the piezoelectric resonator stack 162. The resistor  $R_M$  represents the loss in the piezoelectric resonator stack. The resistor  $R_S$  represents the series electrical resistance of the connections between the terminals 166 and 168 and the piezoelectric resonator stack 162.

FIG. 6 is a schematic block diagram of an embodiment 200 of a bandpass filter according to the invention that incorporates an array of FBAR devices. The bandpass filter 200 is a three-port device that includes input port 224, an output port 228 and a

ground terminal 245 suitable for use in a transceiver as described above with reference to FIG. 4.

The structure of the band-pass filter 230 will now be described. The bandpass filter is composed of the FBAR array 202. The FBAR array is composed of the series FBARs 201, 203 and 205 and the shunt FBARs 207 and 209 connected to form a ladder circuit. The series FBARs are connected in series between the transmit port 224 and the antenna port 228, the shunt FBAR 207 is connected between ground 245 and the node between the series FBARs 201 and 203 and the shunt FBAR 209 is connected between ground 245 and the node between the series FBARs 203 and 205. Thus, in the example shown, the FBARs 201, 203, 205, 207 and 209 form a 2 1/2-stage ladder circuit. However, the number of stages in the ladder circuit is not critical to the invention. The number of full stages, each composed of one series FBAR and one shunt FBAR, and the number of half stages, each composed of one series FBAR or one shunt FBAR, in the FBAR array 202 depends on the desired filter characteristics of the bandpass filter 230 and the characteristics of the individual FBARs constituting the transmit FBAR array 202. For example, in one preferred embodiment, the bandpass filter is a two-stage filter that lacks the FBAR 205.

Figure 7 is a schematic block diagram of an arrangement of multiple receivers that together form a multichannel RF telemetry receiver 500, used to receive and process incoming RF signals. The broadband RF amplifier 504 is configured to receive RF signals from the antenna 502. The thin film bulk acoustic resonator (FBAR) bandpass filter 506 and RF detector 524 are used for default frequency telemetry operations. The remaining thin film bulk acoustic resonator bandpass filters and RF detectors 508/526 and 510/528 are tuned to individual channels in a band of 402-405 MHz (e.g., 403MHz and 405MHz). Although only two filter/detector circuits are shown, the number of such "receiver" or "channels" can be expanded. The RF detector outputs are coupled as inputs to a multiplexing circuit (MUX) 512. The selected MUX input is established under control of the microprocessor 514 and the program stored in ROM 518 and/or RAM 516. The MUX output is coupled to an analog-to-digital converter (ADC) 522 that provides a digitized value of the signal being passed by the selected filter. The processor 514 operating in accordance with a set of program instructions evaluates the noise level of the receiver channel. Each receiver channel is evaluated before a

determination is made as to which channel has the lowest noise level. Thereafter, the output of the bandpass filter in the channel having the best lowest noise and presenting the best signal-to-noise ratio (SNR) is routed through a second multiplexing circuit 550 to the front end 552 of the data receiver. Further communications take place on the selected channel. If desired, the processor can continue to monitor the noise level of the selected channel for suitable quality of the link. If the noise level does not remain below a monitoring noise threshold according to a predetermined criterion, communications can be shifted to a different receiver channel to determine whether a lower noise level condition can be found for further communications.

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The sampling of filtered signals on each channel and an evaluation of the channel noise level can be made using just the ambient signals obtained through antenna 502 and broadband amplifier 504 without a specific RF transmission from the other device. For example, in the programming unit, a test routine can be run wherein the channels are scanned for interference measurement purposes in the absence of an uplink transmission from the implanted medical device. The channels are then ranked according to the general level of noise appearing in the passband of each channel. Or, the channel quality evaluation can be made on the basis of an uplink transmission on each frequency channel and an actual measurement made of the SNR of each channel. The later approach, of course, requires that a tunable transmitter be provided in the implanted medical device. Also, a spectrum analyzer is normally employed to measure the power of the combined signal and noise.

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Figure 8 is a flow diagram 600 depicting a set of instructions in a routine to be executed by the microprocessor in making the evaluation and channel selection. In general, after initialization, when an interrupt occurs, the microprocessor samples the signals present in each of the bandpass filtered channels. The sample is stored in an accumulator within the microprocessor. The microprocessor calculates the noise levels for each channel and then ranks the channels before selecting the channel with the lowest noise level for communication.

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In the case of a programming unit, initialization at block 602 may occur upon power being applied to the programmer 20 or upon the start of a new communication link to an IMD 10. A telemetry communication link is established by placing the programming head over the implant site. The processor then waits for a system interrupt

at block 604 generated from a timer, a user entered keystroke or pen input, or a flag being set from other software programs. The ADC takes a sample of the link noise levels 606, increments a pointer 608, stores the converted value in the accumulator 610. The MUX is stepped to the next channel 612. Also, if the IMD is being stepped to a corresponding transmission frequency, an indication is sent to shift transmission to the next frequency.

At block 614, if all channels have not been sampled, the routine returns to block 604. However, if at block 614 all channels have been sampled, the routine advances to the functional step 616 of calculating the noise levels of all channels. Based upon the calculations of noise, the channels are ranked in order of SNR or general level of noise in the passband. If a communication session with the IMD has been opened previously as indicated by a flag set at block 620, the routine at block 624 directs the programmer to send the rank order list of channel preference to the IMD. The programming unit and IMD then continue link operation on the highest ranked channel. If the link is lost and/or the SNR decreases below some preset value, both switch to the next ranked channel in accordance with block 626. If after, for example, 2 channels have been lost, the programmer will automatically re-initialize the link search routine at block 602. If at block 620 the session has not been open, the session is initialized using channel #1 as the default channel and the list of channels according to rank is sent to the IMD at block 622.

In the case of a multichannel receiver in an IMD, initialization may occur upon detection of an RF signal transmission from the programmer on the default channel. This detection signals the IMD that a communication session is being established and a determination of suitable receiver channel quality is to be undertaken. Thereafter, the IMD sends an acknowledgement command to the programmer and switches to the next receiver channel to obtain a noise level sample of signals appearing within that frequency band. After the IMD captures a sample of the signal on that channel for analysis, it signals the programmer an acknowledgement that it is switching to the next channel. The procedure continues until signals for all receiver channels have been sampled. Following the last acknowledgement, the IMD and programmer go to the default channel. The IMD evaluates the noise levels of the channels and selects a particular channel for the communication session with the programmer. The IMD sends

the programmer an indication of the selected channel and switches to that channel to receive further communications from the programming unit in the communications session. The programmer, upon reception of the indication of the selected channel, makes further transmissions of information during the communication session with the IMD on that channel.

The frequency switching protocol followed by the IMD and programming unit may also be implemented using a sequence of internally timed steps that serve to automatically switch both the IMD receiver and the programming unit transmitter from channel to channel without intervening acknowledgements being sent from the IMD to the programmer.

Another approach to evaluating the noise level on multiple communications channels could be to have the programmer control the channel switching of the IMD receiver by sending commands to switch channels. Thus, after the initial transmission on the default channel and acknowledgement by the IMD, the programmer may send a command to the IMD to switch to the next channel. After a delay sufficient for the IMD to acquire a data sample for noise level analysis, the programmer again commands the IMD to switch to the next channel. The procedure continues until signal samples on all receiver channels have been obtained. The programmer may then interrogate the IMD to determine which channel has been selected for further communication transmissions.

Another protocol that could be followed is to have the IMD obtain channel signal samples and uplink them to the programmer for evaluation and channel selection determination. In this protocol, the programming unit receiver may also undertake to simultaneously sample noise level on each channel and evaluate them along with the noise level samples obtained by the IMD. In this protocol, therefore, the noise level on each receiver channel can be evaluated from the standpoint of both the IMD and the programming unit receivers. The programmer can then make an evaluation and select a channel for further communication transmissions that takes into consideration the best channel from the standpoint of both the reception of the downlink transmission to the IMD and the reception of the uplink transmission to the programmer.

In Fig. 9, another embodiment of a multichannel receiver for an IMD is shown which does not include the channel noise level evaluation function. In this embodiment, an array of thin film bulk acoustic resonator bandpass filters 560-564 is

coupled to the RF antenna in the fashion of Fig. 4. The filter outputs are applied as inputs to a multiplexing circuit 566. Based upon an input from the programming data storage 568, which could be part of ROM/RAM 30 shown in Fig. 2, multiplexing circuit 566 selects the output of one of the bandpass filters. Signals from the selected bandpass filter are routed through to the RF amplifier 570 and the receiver/demodulator circuit 572. Both amplifier 570 and receiver/demodulator 572 may be circuitry in accordance with the receiver shown in Fig. 4.

Using the multichannel receiver embodiment of Fig. 9 in conjunction with a programming unit providing multichannel noise level evaluation in accordance with the circuitry of Fig. 7 and the operational sequence outlined in Fig. 8 permits the IMD to receive channel selection data as another item of programming data. All channel noise level evaluation and determination is preferably done in the programming unit. It is, however, to be recognized that the individual functions of channel data sampling, channel noise level evaluation, and channel selection can be split between the programming unit and the IMD. For example, the channel data samples obtained by the programming unit might be sent along with programming data to the IMD for IMD to do the noise level evaluation and make channel selection determination.

The term signal-to-noise ratio is being used in its common ordinary meaning to those skilled in the art of telecommunications. Because transmitted signals are actually voltages or currents having some varying property that carries intelligence, any other voltages or currents that interact with the signals will tend to mask the intelligence. The unwanted voltages or currents are grouped together under the characterizations of noise and interference. In practical application, some noise is always present and cannot be eliminated completely. As long as the signal strength is sufficiently greater than the noise strength, the signal intelligence will be recoverable. The ratio of the signal strength to the noise strength is obtained by dividing a measurement of the signal strength by a measured value of the noise strength. This is expressed as  $(S+N)/N$ . To get true the signal-to-noise ratio, it is necessary to subtract N from  $(S+N)$  to obtain  $S/N$ . This can be expressed in terms of voltage or power and may be peak values or effective values. High signal-to-noise ratios are desirable because they mean that the noise strength is much weaker than the signal strength and the accuracy of the recovered intelligence is higher. Low signal-to-noise ratios indicate that the noise strength is close to the signal strength.

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and accuracy of the recovered intelligence is compromised. Considerations of making measurements of RF power using a superheterodyne spectrum analyzer are discussed in Hill et. al., "Accurate Measurement of Low Signal-to-Noise Ratios Using a Superheterodyne Spectrum Analyzer," IEEE Transactions on Instrumentation and Measurement, Vol. 39, No. 2, April, 1990.

Federal Communications Commission Regulations found in 47 C.F.R. include provisions that obtain with respect to medical device implant communications in the 402-405 MHz frequency band. These provisions include what is referred to as the "Medical Implant Communications Service" (MICS) and address certain performance characteristics of a communications channel to be used for RF communications with an implanted medical device. The performance characteristics criteria set forth in Section 95.628 can be adopted for determination of the selected channel. Generally, the requirement for an acceptable data transmission channel is that, based on use of an isotropic monitoring system antenna, the monitoring threshold power level must not be more than  $10 \log B(\text{Hz}) - 150 (\text{dB/Hz}) + G(\text{dBi})$ , where B is the emission bandwidth and G is the medical implant programmer transmitter antenna gain relative to an isotropic antenna. The emission bandwidth B is measured as the width of the signal frequency content between points on either side of the carrier center frequency that are 20 dB down relative to the maximum level of the modulated carrier.

While the present invention has been described herein with reference to particular, preferred embodiments and applications thereof, numerous variations and modifications could be made thereto by those skilled in the art without departing from the spirit and scope of the invention as claimed. Accordingly, the scope of the invention should be determined with reference to the claims set forth below.